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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,887	03/05/2002	Benjamin Eithan Reubinoff	13164A	7135

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Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,887	REUBINOFF ET AL.	
	Examiner	Art Unit	
	Joseph T. Weitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application filed March 5, 2002, is a divisional of 09/436,164, filed November 9, 1999, now US Patent 6,875,607, which claims benefit of foreign applications PP7009, filed November 9, 1998, and PQ2852, filed September 15, 1999, both filed in Australia.

Applicants' amendment filed March 10, 2006 has been received and entered. Claims 1-45 have been canceled. Claims 46-54 have been added. Claims 46-54 are pending and currently under examination.

Election/Restrictions

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Newly submitted claims 46-54 are encompassed by the invention originally claimed.

Claim Objections

Claims 51-54 are objected to because the first presentation of an abbreviated term should be denoted by setting forth the full name indicating the term to be used subsequently, in particular the embodiments encompassing "EG". It appears that EG refers to ethylene glycol, however this is not an art accepted abbreviation.

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Appropriate correction is required. is withdrawn.

The amendment to the claims has addressed the basis of the objection.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 46 be found allowable, claim 50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In this case, claim 50 appears to only recite inherent properties of a pluripotent stem cell, and does not appear to further limit the method of claim 46 in what method steps are practiced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, newly submitted claims recite generally components comprised in a vitrification solution however the specification only supports the presences of the components in two specific solutions, and does not provide the basis for simply listing the names of the components, nor for ranges or combinations where the concentration of one component is fixed and others are not. General support for the amendment can be found on page 30, however a careful comparison indicates that the claims as written are not supported by this disclosure.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 51-54 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. In particular, the specification teaches that the process of freezing cells can result in cell death, and the process and materials used are critical in obtaining viable cells upon thawing. In this case, the breadth of the claims is large encompassing any concentration or amount of DMSO or EG which are know to be toxic to cells, and any concentration of sucrose and FBS which are also important to the culture and maintenance of the cells upon thawing.

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While it would be easy to make solutions with multiple variations in the comprised components, it would constitute an undue burden to test all of these solutions with no expectation that it would successfully preserve the ES cell.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 recites the limitation "the vitrification solution" and is dependent on

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claim 51, however there are two vitrification solutions recited in claim 51. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims rejected under 35 U.S.C. 102(b) as being anticipate by Thomson *et al.* (Science 282:1145-1147-IDS Reference) and Thomson (US Patent 6,200,806-IDS Reference) is withdrawn.

Claims encompassing frozen vitrified cells have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomosn *et al.* (Science 282:1145-1147 or US Patent 6,200,806-IDS References) and Vajta *et al.*

Newly submitted claims encompass preserving human embryonic stem cells in clumps by vitrification, in particular by the OPS methodology. It is noted that different from previous claims, the present claims require that “a clump of hES cells” be obtained and vitrified.

Thomson teaches that the human embryonic cell lines disclosed in the reference were cryopreserved, and that after freezing the cell lines could be propagated without any apparent affect on the pluripotential characteristics of the cells (US Patent columns 14-15). Moreover, Thomosn teaches that human ES cells are cultured and harvested in clumps of cells. It is noted that Thomson does not specifically state that the number of cells in a clump, however given the breadth of “about 100” a reasonable interpretation would be any number considered a clump when culturing ES cells. Again, at the time of filing cryopreserving a cell or cell line was routine in the art. Thomosn does not teach the specific method(s) of cryopreservation that are used, however it would be routine to use one known in the art that was successfully used to preserve other cell lines, in particular methods that were used for embryonic like cells. At the time of filing Vajta *et al.* teach that vitrification can be used for cryopreserving embryonic cells, and demonstrates the effectiveness by reducing to practice the freezing of porcine embryos by the OPS method. The method set forth in claim 46 is broad and simply requires that the cell

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undergoes vitrification. The instant specification clearly teaches that the methodology contemplated is not new and refers to the methods taught by Vajta *et al.* (page 25, lines 2-4). While Vajta *et al.* teach that vitrification can be used for cryopreserving embryonic cells, and that it can be extended to other mammals, they do not specifically teach that it was practiced with human cells. Thomson does not teach the specific method(s) of cryopreservation that are used, however it would be routine to use one known in the art that was successfully used to preserve other cell lines, in particular methods that were used for embryonic like cells. Thomson teaches the methods of culture which used DMEM, however the media used is not the same as that used in the vitrification solution of Vajta *et al.* With respect to the specific components used in the vitrification methods, it is noted that Vajta *et al.* does not teach the use of DMEM, and these claims are not subject to the rejection.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the method of cryopreservation taught by Vajta *et al.* as one of the specific methods taught by Thomson for cryopreserving embryonic cells. One having ordinary skill in the art would have been motivated to use any specific method of cryopreservation known in the art, and there would have been a reasonable expectation of success given the results of Vajta *et al.* and the general disclosure of Thomson *et al.* to successfully cryopreserve a human embryonic stem cell.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

No claim is allowed.

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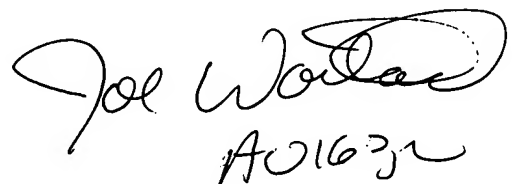
As noted previously, the methods of cryopreserving a cell contemplated and used in the instant specification are not new and specifically refer to those disclosed by Vajta *et al.* Further, while Vajta *et al.* teaches generally that the method can be used in preserving undifferentiated embryonic cells (*i.e.* frozen embryos), Reubinoff *et al.* (Hum Reprod 16(10):2187-2194) teach that this method, the Open pulled Straw method for the vitrification of cells, can be successfully used in cryopreserving undifferentiated stem cells. Importantly, as suggested in the present specification, it is taught that the method does not result in any modification of the cells that are frozen, thus the methods of freezing would not provide a product that is distinguishable from that with which one started.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Handwritten signature of Joe Woitach and Art Unit 1632.